510(k) SUMMARY

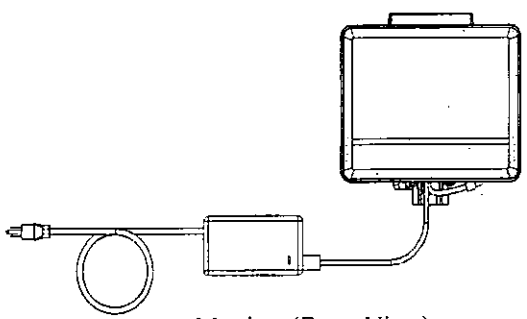
AUG 3 1 2011

K112376

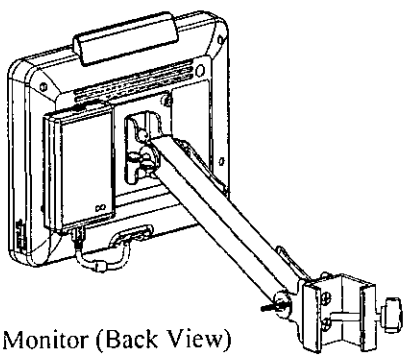
Submitter:	CIRCA Scientific, LLC 14 Inverness Drive East, Suite H-240 Englewood, CO 80112 (303) 951-8767
Date Prepared:	July 28, 2011
Trade/Device Name:	S-Cath™ Esophageal Temperature Probe and Temperature Monitoring System
Regulation Number:	880.2910
Regulation Name:	Clinical electronic thermometer
Regulatory Class:	Class II
Product Code:	FLL
Predicate Device:	Esophageal/Rectal Temperature Probe (510(k) K863646), Temperature Monitor (510(k) K913083)

DEVICE DESCRIPTION

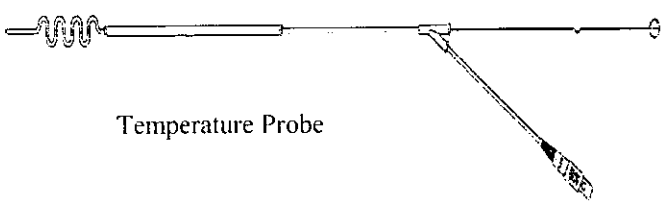
The CIRCA Scientific Temperature Monitoring System consists of: touch-screen monitor, interconnect cable, and temperature probe.



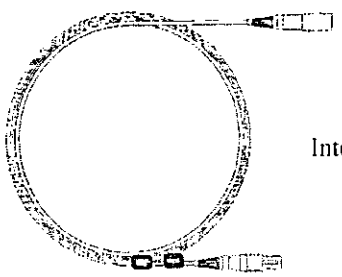
Monitor (Front View)



Monitor (Back View)



Temperature Probe



Interconnect Cable

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The monitor displays 12 temperature probe sensor readings (°C), the maximum temperature of all sensors, and contains an alarm system with user-selected levels.

The S-Cath™ Esophageal Temperature Probe provides continuous temperature measurement (°C) and operates in direct mode. The probe contains 12 thermistor sensors located along an s-curve. The sensors measures temperature by a resistor that is sensitive to temperature changes. The probe is connected to the monitor by using an interconnect cable. The 10Fr diameter probe is placed inside the esophagus.

INDICATIONS FOR USE

Esophageal Temperature Probe:

The Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus.

Temperature Monitor:

Display continuous temperature measurement (°C) from 12-sensor temperature probe.

TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE

Legally Marketed Electronic Thermometer to Which Substantial Equivalence is Claimed: Smiths Medical Level 1® Esophageal/Rectal Temperature Probe (510(k) K863646), Smiths Medical Bi-Temp Temperature Monitor (510(k) K913083). The probe and monitor are originally listed under Respiratory Support Products, Inc. (RSP).

ELEMENT OF COMPARISON	SUBJECT DEVICE	CLAIMED SE DEVICE
Thermometer type	Esophageal	Esophageal / Rectal
Intended Uses	Continuous patient temperature monitoring, designed for insertion into the esophagus.	Continuous patient temperature monitoring, designed for insertion into the esophagus, nasopharynx, or rectum.
Labeling	Temperature Probe labeled for single-use. Package label includes product identification, lot number. Instructions for use established.	Temperature Probe labeled for single-use. Package label includes product identification, lot number. Instructions for use established.
Components	Temperature Probe(10Fr OD, 30.5" total length); Interconnect Cable (10' Length); Monitor (10.2" W x 7.8" H x 3.25" D).	Temperature Probe (9Fr and 12Fr OD, 30.5" total length; Interconnect Cable (length not specified); Monitor (6.1" W x 3.4" H x 6.3" D).
Sensor	NTC Thermistor (accurate to ± 0.2°C within temperature range)	NTC Thermistor (accurate to ± 0.2°C within temperature range)

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Signal processing and display	Actual temperature is a function of the thermistor resistance. Temperature displayed in 0.1°C increments. 1 input (single probe) available. 12 sensors per probe displayed. LCD Display includes user-selected alarm limits.	Actual temperature is a function of the thermistor resistance. Temperature displayed in 0.1°C increments. 2 inputs (2 probes) available. 1 sensor per probe displayed. LCD Display includes user-selected alarm limits.
Power requirements	100 – 240 Vac	Alkaline D (4 batteries)
Materials (Patient Contacting)	Flexible Polyether and Rigid Polyamide PEBAX®	Polyvinyl Chloride (PVC)
Temperature Range	25°C to 45°C	5°C to 45°C
Ambient Temperature Environment	No special ambient temperature range is specified for the device.	No special ambient temperature range is specified for the device.
Accuracy	The accuracy within the rated output range in normal use is not greater than 0.3°C (ISO 80601-2-56:2009 requirement for clinical thermometers).	The accuracy within the rated output range in normal use is not greater than 0.3°C (ISO 80601-2-56:2009 requirement for clinical thermometers).
Precision and Repeatability	0.1°C	Not specified
Response Time	Heating transient response time is approximately 7 seconds and cooling transient response time is approximately 4.5 seconds. (Note: time is for probe plunged from reference water bath to a water bath with a 2°C differential.)	Heating transient response time is approximately 29 seconds and cooling transient response time is approximately 18 seconds. (Note: time is for probe plunged from reference water bath to a water bath with a 2°C differential.)
Other Capabilities	Device fully complies with IEC 60601-1:1988 + A1:1991 + A2:1995. Electromagnetic compatibility fully complies with IEC 60601-1-2:2007.	Electrical leakage current of the device (sensor and PVC tube) when used with Level 1 monitor and cable, comply with IEC 601-1/EN 60601-1.
Comparison Discussion	The S-Cath Esophageal Temperature Probe and Monitor is substantially equivalent to the predicate Smiths Medical Esophageal/Rectal Temperature Probe and Monitor for the following elements: - Thermometer type; - Intended uses; - Labeling; - Components; - Sensor; - Signal process and display; - Temperature range; - Ambient temperature environment; - Accuracy.	

	The following differences are noted but do not affect substantial equivalence of safety and effectiveness: - Power requirements: SE device uses batteries while S-Cath connects to hospital mains supply (100 – 240 Vac). It has been evaluated to IEC 60601-1 and meets electrical safety requirements. - Materials (Patient Contacting): material of S-Cath PEBAX was chosen for its flexibility and is used for other devices such as urology catheter. It has been evaluated to ISO 10993-1 and meets biocompatibility requirements. - Response Time: S-Cath provides a faster response time than predicate device.

NON-CLINICAL PERFORMANCE DATA

The following performance testing was performed per Standard ISO 80601-2-56 / First Edition 2009-10-01 *Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement* to establish and compare performance characteristics to the predicate device:

- Accuracy of the device.
- Precision and repeatability of the device.
- Time Response.

In addition, the device has been assessed against the standards below. The device has been tested and meets physical, operational, and biological specifications.

- ISO 10993-1 / 2009 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- IEC 60601-1 / 1988 + Amendment 1 / 1991-11 + Amendment 2 / 1995 *Medical electrical equipment – Part 1: General requirements for safety*
- IEC 60601-1-2 / Edition 3:2007-03 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*
- IEC 60601-1-4 / 2000 Consol. Ed 1.1 *Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems*
- ISO 15223-1 / First Edition:2007 *Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements*
- ISO 14971 / 2007 *Medical devices – Application of risk management to medical devices*

CLINICAL PERFORMANCE DATA

No clinical studies were performed to demonstrate substantial equivalence.

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CONCLUSION OF SAFETY AND EFFECTIVENESS

The successful completion of:

- accuracy, precision and repeatability, and time response performance tests;
- compliance to biological standard ISO 10993-1; and
- compliance to electrical safety standards IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-4;

demonstrate the safety and effectiveness of the CIRCA Scientific Esophageal Temperature Probe and Monitor when used for the defined indications for use, and demonstrate that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Circa Scientific, LLC
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

AUG 31 2011

Re: K112376
Trade/Device Name: S-Cath™ Esophageal Temperature Probe and Temperature Monitoring System
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: August 16, 2011
Received: August 17, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112376

Indications for Use:

Esophageal Temperature Probe:

The Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus.

Temperature Monitor:

Display continuous temperature measurement (°C) from 12-sensor temperature probe.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 8/31/11

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112376